

## Clinical Policy: Levocetirizine (Xyzal)

Reference Number: CP.CPA.08

Effective Date: 08.01.18

Last Review Date: 08.19

Line of Business: Commercial

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

### Description

Levocetirizine (Xyzal<sup>®</sup>) is a histamine H1-receptor antagonist.

### FDA Approved Indication(s)

Xyzal is indicated in adults and children 6 months of age and older for the treatment of:

- Relief of symptoms associated with seasonal and perennial allergic rhinitis
- Uncomplicated skin manifestations of chronic idiopathic urticaria

### Policy/Criteria

*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of health plans affiliated with Centene Corporation<sup>®</sup> that Xyzal is **medically necessary** when the following criteria are met:

#### I. Initial Approval Criteria

##### A. Allergic Rhinitis, Chronic Idiopathic Urticaria (must meet all):

1. Diagnosis of allergic rhinitis or chronic idiopathic urticaria;
2. Age  $\geq$  6 months;
3. Failure of two oral antihistamines (e.g., cetirizine, loratadine, fexofenadine) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
4. Dose does not exceed 5 mg per day.

**Approval duration: Length of Benefit**

##### B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial.

#### II. Continued Therapy

##### A. Allergic Rhinitis, Chronic Idiopathic Urticaria (must meet all):

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 5 mg per day.

**Approval duration: Length of Benefit**

**B. Other diagnoses/indications (must meet 1 or 2):**

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.  
**Approval duration: Duration of request or 12 months (whichever is less);** or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial.

**III. Diagnoses/Indications for which coverage is NOT authorized:**

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial or evidence of coverage documents.

**IV. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*

FDA: Food and Drug Administration

*Appendix B: Therapeutic Alternatives*

*This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.*

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
cetirizine (Zyrtec®)	≥ 6 years: 5 mg to 10 mg QD 1-5 years: 2.5 to 5 mg QD	≥ 6 years: 10 mg/day 1-5 years: 5 mg/day 6 months and older: 2.5 mg/day
loratadine (Claritin®)	≥ 6 years: 10 mg QD 2-5 years: 5 mg QD	≥ 6 years: 10 mg/day 2-5 years: 5 mg/day
fexofenadine (Allegra®)	≥ 12 years: 60 mg BID or 180 mg QD 6-11 years: 30 mg BID	≥ 12 years: 180 mg/day 2-11 years: 60 mg/day 6 months to < 2 years: 30 mg/day

*Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.*

*Appendix C: Contraindications/Boxed Warnings*

- Contraindication(s):
  - Known hypersensitivity to levocetirizine or any of the ingredients of Xyzal, or to cetirizine
  - Children 6 months to 11 years of age with impaired renal function
  - End-stage renal disease at less than 10 mL/min creatinine clearance or patients undergoing hemodialysis
- Boxed warning(s): none reported

**V. Dosage and Administration**

Drug Name	Dosing Regimen	Maximum Dose
Levocetirizine (Xyzal)	≥ 12 years: 5 mg PO QD 6-11 years: 2.5 mg PO QD 6 months-5 years: 1.25 mg PO QD	≥ 12 years: 5 mg/day 6-11 years: 2.5 mg/day 6 months-5 years: 1.25 mg/day

**VI. Product Availability**

- Tablet: 5 mg
- Oral solution: 2.5 mg/5 mL (0.5 mg/mL)

**VII. References**

1. Xyzal Prescribing Information. Bridgewater, NJ: Sanofi-Aventis U.S. LLC; March 2019. Available at <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=a6ca9f62-c065-4eda-bf95-97165cdd5fec>. Accessed April 22, 2019.
2. Xyzal Allergy 24HR Prescribing Information. Chattanooga, TN: Chatten, Inc.; March 2017. Available at <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=8be45c2a-1eca-4a00-81b9-f7babdbdcd41>. Accessed April 22, 2019.
3. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2019. Available at: <http://www.clinicalpharmacology-ip.com>. Accessed April 22, 2019.
4. Wallace DV, Dykewicz MS, Bernstein DI, et al. The diagnosis and management of rhinitis: an updated practice parameter. J Allergy Clin Immunol. 2008. 122(2 Suppl): S1-S84.
5. Wallace DV, Dykewicz MS, Oppenheimer J et al. Pharmacologic treatment of seasonal allergic rhinitis: synopsis of guidance from the 2017 Joint Task Force on Practice Parameters. Ann Intern Med. 2017 Dec 19;167(12):876-881. doi: 10.7326/M17-2203.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
3Q 2018 annual review: policy split from CP.CPA.18 into individual Xyzal policy; no significant changes; references reviewed and updated.	04.18.18	08.18
3Q 2019 annual review: no significant changes; references reviewed and updated.	04.22.19	08.19

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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